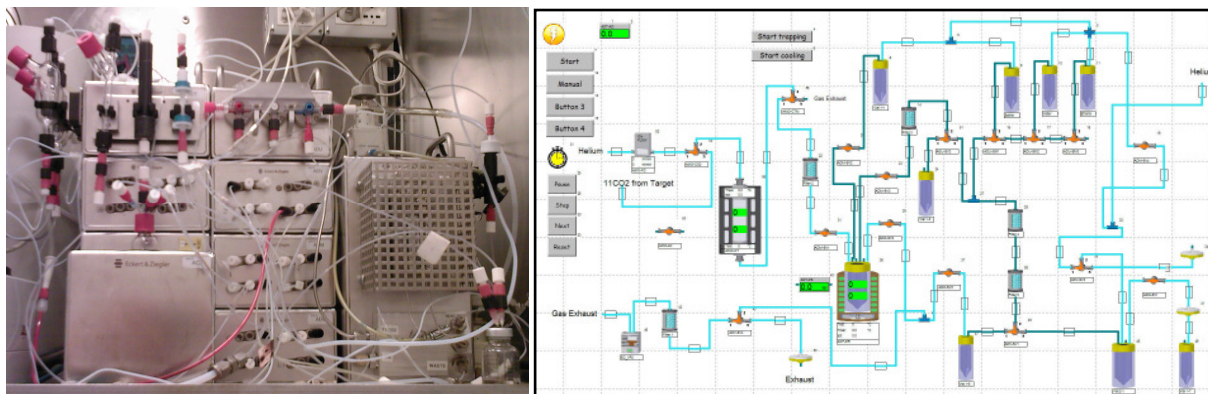


Modular-Lab

For [^{11}C]Methyl Iodide – “wet chemistry” approach



Example: Display Scheme for the [^{11}C]Choline

The Modular-Lab technology offers a reliable way for the synthesis of Carbon-11 based tracers for clinical use.

■ Application

Carbon-11 - characterized by its relatively short half life - has the advantage to be applicable for repeated PET studies while still allowing multi-step radiosynthesis sequences. [^{11}C]methyl iodide (^{11}C CH₃I) is the most important and frequently used secondary ^{11}C -labelling precursor. Its versatility allows the synthesis of a wide variety of PET tracers.

■ Technology

[^{11}C]methyl iodide can be easily produced with the automated syn-

thesis device Modular-Lab* resulting in high radiochemical yields and high specific radioactivity. The Modular-Lab technology for the production of [^{11}C] methyl iodide is based on the liquid-phase method. Instead of using liquid nitrogen for [^{11}C]CO₂ trapping, the cyclotron produced [^{11}C]CO₂ is reversibly adsorbed to molecular sieves. After controlled release by heating the molecular sieves, [^{11}C]CO₂ is converted into [^{11}C]CH₃I by conventional LiAlH₄/HI reaction in one pot. The small and simple setup fits into every Hot Cell. The hardware configuration consists of individual modules (e.g. Peltier Reactor Module, Carbon Trapping Module, different Valve Modules, Vial Holder Modules) for unit operations, which can be easily combined using an integrated bus-system for plug & play operations.

The produced [^{11}C]CH₃I is then available for tracer synthesis. If desired more modules can be easily included into the system. The products can be purified by SPE or, if necessary, an HPLC can be easily integrated into the system.

■ Standard Regulatory Compliance

The Modular-Lab Software combines easy programming via a self-explanatory graphical user interface with the highest standards compliant with GMP, GAMP 4/5 and 21 CFR part 11 regulations. Access control with four defined security levels meets all demands for the security of the process data and the application-specific setup. The logging of all system and user operations runs fully automatically in Audit Trails.

*patent pending

■ Key Features

- Fully automated synthesis process, no user intervention necessary
- Fully automated cleaning routine after each process to ensure a minimum of chemical or bacterial contamination of the system
- Plug & play system setup through integrated bus-system
- Traceability of the complete process, including documentation of all process parameters and functions
- Upgradeable for further applications
- Synthesis time for [¹³C]methyl iodide: less than 12 minutes (further data upon request)

■ Modular-Lab Components

Peltier Reactor Module (PRM) with Lift	<p>Dimensions: 130 x 230 x 156 mm</p> <p>Heating and cooling with thermoelectric Peltier elements from -40°C to +150°C (with heat exchanger, no liquid nitrogen needed for cooling). Reactor can be equipped with activity detector, camera, stirrer, thermo sensor inside reactor block and a lift. Lead-shielding of activity detector and electronics is included. Temperature and pressure measurement inside reaction vial is possible. Vials from 1 to 24 mL can be used with different adapter rings.</p>
Carbon Trapping Unit (CTM)	<p>Dimensions: 130 x 130 x 234 mm</p> <p>Trapping of [¹³C]CO₂ is achieved by a molecular sieve (60-80 mesh) at room temperature. The column for heating is supplied by VICI with following attributes: 1/4"x5cm and 1/16" tube fitting. Compressed air influx through 4mm tubing and 2/2 way valve. Gas distribution is performed by a valve manifold with two types of connectors: 1/16" tube fitting to waste, reactor and column; 1/8" tube fitting for [¹³C]CO₂ and Helium gas. The gases are distributed by 3/2 way valves. The Helium flow is especially controlled by an integrated Helium flow controller ranging from 0 to 150 ml/min (max. pressure: 3 bar).</p>
Solenoid Valve Module (SVM)	<p>Dimensions: 130 x 130 x 78 mm</p> <p>With 4 valves (3/2-way or 2/2-way) for liquid transport. Standard UNF connectors at front. Easy to access for mounting of "finger tight" fittings. Optional one valve (barbed fitting) at back for gas transport. Bürkert 6604</p>
Stopcock Manifold Module (SMM)	<p>Dimensions: 130 x 130 x 78 mm</p> <p>Holder and adapter for quick mounting of stopcock manifold. Standard stopcock manifold with Luer connectors for medical application (one way, sterile) is used. Stopcocks are driven by servo motors.</p>
Vial Holder Module (VHM) & Vial Holder Plate (VHP)	<p>Dimensions: 130 x 130 x 78 mm</p> <p>The Vial Holder Module is designed to hold up to either 3 vials or cartridges. Various holders are available. The holders can easily be adjusted, depending on the size of the vials and the required space. Activity detectors are built inside to continuously monitor the activity within the vial.</p>
Electrical Cabinet (EC)	Control Unit
Heat Exchanger (HE)	for temperatures to -40°C
Modular-Lab Software	GMP, GAMP 4/5 and 21 CFR part 11 compliant
Further components:	Pressure sensors, chemical absorber trap, heat exchanger, pressure controller

Please note: Any type of tubing, connectors, vials and valves can be ordered with the system.

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